OIPE 4288

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Norman L. Anderson

Examiner:

Hines, Jana A.

Serial No.:

10/676,005

Art Unit:

1645

Filed:

October 2, 2003

Confirmation No.:

6420

For:

HIGH SENSITIVITY QUANTITATION OF PEPTIDES BY MASS

SPECTROMETRY

U.S. Patent and Trademark Office Customer Service Window, Mail Stop Amendment Randolph Building 401 Dulany Street Alexandria, VA 22314

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(c)

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant(s) hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98.

- [x] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form PTO/SB/08 is enclosed.
- [] No copies of the publications listed on the attached Form PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No. ____ to which the above-identified application claims priority under 35 U.S.C. §120.
- [x] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

| Publication(s) | listed on the attache | ed Form PTO/SB/08 | were cited in a |
|-----------------------|-----------------------|--------------------|-------------------|
| foreign search or | examination report | corresponding to _ | application |
| serial no and | mailed on | 07/27/2006 JADDO1 | 60000001 10676005 |

| [] | Enclosed is a copy | of a non-E | nglish pul | olica | tion(\$93 <u>6</u> | Pursua | ant to §60 | 7930.00 OP |
|----|--------------------|---------------|------------|-------|--------------------|-----------|------------|-------------------|
| | of the M.P.E.P., | Applicant | submits | the | attached | foreign | search | or |
| | examination report | , which cites | s such noi | n-Eng | glish langı | iage publ | lication(s | a). |

| | Enclosed is a copy of a non-English publication(s) English language publication (copy enclosed) claims priority from this non-English publication. |
|----|--|
| [] | Enclosed is an explanation of non-English publication(s) for which an English translation is not available. |
| [] | Enclosed is an English translation of non-English publication(s) cited in the attached Form PTO/SB/08. |
| [] | Enclosed is a copy of pending patent Application Serial No |

This Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of a final action under 37 C.F.R. §1.113; a notice of allowance under 37 C.F.R. §1.311; or an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

- [x] Fee under 37 C.F.R. §1.17(p) in the amount of \$180.00; or
- [] Statement as specified in 37 C.F.R. §1.97(e):
 - [] Each item of information contained in the Information Disclosure Statement cited herein was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
 - [] No item of information contained in the Information Disclosure Statement submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08 to the undersigned.

Dated: July 26, 2006

COOLEY GODWARD LLP ATTN: Patent Group The Bowen Building 875 15th Street NW, Suite 800 Washington, DC 20005-2221

Tel: (703) 456-8000 Fax: (202) 842-7899

296693 v1/RE

Respectfully submitted,

COOLEY GODWARD LLP

By:

Timothy D. Ford Reg. No. 47,567

| | 1 | · | |
|-------|-----------------------------------|------------------------|--------------------|
| C. I | stitute for form 1449A/PTO | MADEMAN | Complete if Known |
| Suc | istitute for form 1449A/F 10 | Application Number | 10/676,005 |
| IN | FORMATION DISCLOSURE | Filing Date | October 2, 2003 |
| | FATEMENT BY APPLICANT | First Named Inventor | Norman L. Anderson |
| 31 | | Group Art Unit | 1645 |
| | (use as many sheets as necessary) | Examiner Name | Hines, Jana A. |
| Sheet | 1 of 4 | Attorney Docket Number | ANDE-001/04US |

| | U.S. PATENT DOCUMENTS | | | | |
|-----------------------|-----------------------|---|--|--|--|
| Examiner Initials* | Cite No.1 | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| Intidio | 1. | 5,955,729 | 09-21-1999 | Nelson et al. | |
| | 2. | 6,391,649 | 05-21-2002 | Chait et al. | |
| | 3. | 6,649,419 | 11-18-2003 | Anderson | |
| | 4. | 6,783,672 | 08-31-2004 | Tubbs et al. | |
| | 5. | 6,811,689 | 11-02-2004 | Zhang et al. | |
| | 6. | 6,864,099 B2 | 03-08-2005 | Regnier | |
| | 7. | 6,872,575 B2 | 03-29-2005 | Regnier | |
| | 8. | 6,974,704 | 12-13-2005 | Nelson et al. | |
| | 9. | 2001/0021535 A1 | 09-13-2001 | Nelson et al. | |
| | 10. | 2001/0312279 | 08-14-2001 | Gygi | |
| | 11. | 2002/0055186 | 05-09-2002 | Barry et al. | |
| | 12. | 2002/0110904 A1 | 08-15-2002 | Nelson et al. | |
| | 13. | 2002/0127739 A1 | 09-12-2002 | Pieper et al. | |
| _ | 14. | 2002/0164818 A1 | 11-07-2002 | Gruber et al. | |
| | 15. | 2003/0044848 | 03-06-2003 | Rush et al. | |
| | 16. | 2003/0129769 | 07-10-2003 | Regnier | |
| | 17. | 2004/0029292 | 02-12-2004 | Joos et al. | |
| | 18. | 2004/0038307 | 02-26-2004 | Lee et al. | |
| | 19. | 2004/0043497 | 03-04-2004 | Feuer et al. | |
| | 20. | 2004/0072251 A1 | 04-15-2004 | Anderson | |
| | 21. | 2004/0180380 | 09-16-2004 | Lee et al. | |
| | 22. | 2004/0214338 A1 | 10-28-2004 | Borchers | |
| | 23. | 2005/0069911 | 03-31-2005 | Lee et al. | |
| | 24. | 2005/0202506 | 09-15-2005 | Cantor | |
| | 1 | | | | |
| | + | | | | |
| | + | | | | |
| | + | | | | |
| | + | | <u> </u> | | ` |
| | + | | † | | |
| | 1 | | | | |
| | + | <u> </u> | | | |
| | - | | | | |
| | | | | | |
| | + | | 1 | | |

| 1 | Examiner | Date | • |
|---|-----------|------------|---|
| 1 | Signature | Considered | |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Unique citation designation number (optional). See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

| | ubstitute for form 1449A/PTO | | Complete if Known |
|------------------------|-----------------------------------|------------------------|--------------------|
| 3 | dostitute for form 1449A/1 10 | Application Number | 10/676,005 |
| I | NFORMATION DISCLOSURE | Filing Date | October 2, 2003 |
| STATEMENT BY APPLICANT | | First Named Inventor | Norman L. Anderson |
| 1 ` | | Group Art Unit | 1645 |
| 1 | (use as many sheets as necessary) | Examiner Name | Hines, Jana A. |
| Sheet | 2 of 4 | Attorney Docket Number | ANDE-001/04US |

| | | | FOREIGN PA | TENT DOCUMENTS | | |
|-----------------------|--------------|---|--------------------------------|---|---|----------------|
| Examiner Initials* | Cite No.1 | Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ² |
| | 25. | WO 03016861 | 02-27-2003 | Gygi et al. | | <u></u> |

| | La | OTHER - NON PATENT LITERATURE DOCUMENTS | |
|-----------------------|--------------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | 26. | Purification, KingFisher 96, New Product Brochure, pp. 28-33. | |
| | 27. | Dynabeads, Dynal Biotech, pp. 1-6. | |
| | 28. | ADKINS, J. N. et al., "Toward a Human Blood Serum Proteome," Molecular & Cellular Proteomics 1.12, 2002, pp. 947-955, Vol. 1. | |
| | 29. | AMINI, A. et al., "Simplification of Complex Tryptic Digests for Capillary Electrophoresis by Affinity Selection of Histidine-Containing Peptides with Immobilised Metal Ion Affinity Chromatography," Journal of Chromatography B., 2002, pp. 35-44, Vol. 772. | |
| | 30. | ANDERSON, N. L. et al., "The Human Plasma Proteome, History, Character, and Diagnostic Prospects," Molecular & Cellular Proteomics 1.11, 2002, pp. 845-867, Vol. 1. | |
| | 31. | ANDERSON, N. L. et al., "The Human Plasma Proteome, A Nonredundant List Developed by Combination of Four Separate Sources," Molecular & Cellular Proteomics 3.4, 2004, pp. 311-326, Vol. 3. | |
| | 32. | ANDERSON, N. G. et al., "Analytical Techniques for Cell Fractions, XIX, The Cyclum: An Automatic System for Cyclic Chromatography," Analytical Biochemistry, 1975, pp. 159-174, Vol. 66. | |
| | 33. | ANDERSON, N. G. et al., "Analytical Techniques for Cell Fractions, XX, Cyclic Affinity Chromatography: Principles and Applications," Analytical Biochemistry, 1975, pp. 371-393, Vol. 68. | |
| | 34. | ANDERSON, L. et al., "High Resolution Two-Dimensional Electrophoresis of Human Plasma Proteins," Proc. Natl. Acad. Sci. USA, December 1977, pp. 5421-5425, Vol. 74, No. 12. | |
| | 35. | ANDERSON, N. L. et al., "Global Approaches to Quantitative Analysis of Gene-Expression Patterns Observed by use of Two-Dimensional Gel Electrophoresis," Clinical Chemistry, 1984, pp. 2031-2036, Vol. 30, No. 12. | |
| , | 36. | ANDERSON, N. L. et al., "Effects of Toxic Agents at the Protein Level: Quantitative Measurement of 213 Mouse Liver Proteins Following Xenobiotic Treatment," Fundamental and Applied Toxicology, 1987, pp. 39-50, Vol. 8. | |
| | 37. | ANDERSON, N. L. et al., "A Two-Dimensional Gel Database of Human Plasma Proteins," Electropharesis, 1991, pp. 883-906, Vol. 12. | |
| | 38. | ANDERSON, L. et al., "Effects of Oltipraz and Related Chemoprevention Compounds on Gene Expression in Rat Liver," 1995, J. Cell Biochem, pp. 108-116, Supplement 22. | |
| | 39. | ANDERSON, N. L., et al., "The Effects of Peroxisome Proliferators on Protein Abundances in Mouse Liver," Toxicology and Applied Pharmacology, 1996, pp. 75-89, Vol. 137. | |
| | 40. | BEYNON, R. J. et al., "Multiplexed Absolute Quantification in Proteomics using Artificial QCAT Proteins of Concatenated Signature Peptides," Nature Methods, August 2005, pp. 587-589, Vol. 2, No. 8. | |
| | 41. | BISWAL, S. L. et al., "Micromixing with Linked Chains of Paramagnetic Particles," Analytical Chemistry, November 1, 2004, pp. 6448-6455, Vol. 76, No. 21. | |
| | 42. | BURROUGHS, N. J. et al., "Discriminating Self From Nonself with Short Peptides from Large Proteomes," Immunogenetics, 2004, pp. 311-320, Vol. 56. | |
| | 43. | CHAKRABORTY, A. et al., "Global Internal Standard Technology for Comparative Proteomics," Journal of Chromatography A, 2002, pp. 173-184, Vol. 949. | |
| | 44. | DOHERTY, N. S. et al., "Analysis of Changes in Acute-Phase Plasma Proteins in an Acute Inflammatory Response and in Rheumatoid Arthritis Using Two-Dimensional Gel Electrophoresis," Electrophoresis, 1998, pp. 355-363, Vol. 19. | |
| | 45. | GENG, M. et al., "Proteomics of Glycoproteins Based on Affinity Selection of Glycopeptides from Tryptic Digests," Journal of Chromatography B, 2001, pp. 293-306, Vol. 752. | |

| + | ı |
|---|---|
| | |

Complete if Known Substitute for form 1449A/PTO 10/676,005 Application Number INFORMATION DISCLOSURE Filing Date October 2, 2003 First Named Inventor Norman L. Anderson STATEMENT BY APPLICANT Group Art Unit 1645 (use as many sheets as necessary) Hines, Jana A. Examiner Name ANDE-001/04US 3 of 4 Attorney Docket Number Sheet

| HURST, G. B. et al., "Analysis for TNF-α Using Solid-Phase Affinity Capture with Radiolabel and MALDI-MS Detection," Analytical Chemistry, October 15, 1999, pp. 4727-4733, Vol. 71, No. 20. | |
|---|---|
| JI, J. et al., "Strategy for Qualitative and Quantitative Analysis in Proteomics Based on Signature Peptides," Journal of Chromatography B, 2000, pp. 197-210, Vol. 745. | |
| KISELAR, J. G. et al., "Direct Identification of Protein Epitopes by Mass Spectrometry Without Immobilization of Antibody and Isolation of Antibody – Peptide Complexes," Analytical Chemistry, May 1, 1999, pp. 1792-1801, Vol. 71, No. 9. | , |
| Electrospray Mass Spectrometry," Clinical Chemistry, 2001, pp. 513-518, Vol. 47, No. 3. | |
| August 20, 2002, pp. 11049-11054, Vol. 99, No. 17. | |
| PNAS, June 11, 2002, pp. 7900-7905, Vol. 99, No. 2. | |
| of Peptides with a Fragmentation-Directing Moiety," Analytical Chemistry, September 1, 2000, pp. 4047-4057, Vol. 72, No. 17. | |
| Proteomics, 2002, pp. 441-446, Vol. 2. | |
| Protein Identification at Low-Femtomole to Subfemtomole Levels," Analytical Chemistry, 1999, pp. 2858-2865, Vol. 71. | |
| USA, June 1999, pp. 6591-6596, Vol. 96. | |
| to Expression Proteomics," Molecular & Cellular Proteomics 1.5, 2002, pp. 376-386, Vol. 1. | |
| 2002, pp. 572-577, Vol. 359. | |
| Analysis of Complex Protein Mixtures," Analytical Chemistry, October 1, 2002, pp. 4969-4979, Vol. 74, No. 19. | |
| Analytical Chemistry, November 1, 2004, pp. 6239-6246, Vol. 76, No. 21. | |
| 368, Vol. 924. | |
| Clinical Chemistry, 1980, pp. 30-36, Vol. 26, No. 1. | |
| and Complex Mixtures of Peptide-Ligands," Analytical Biochemistry, 1999, pp. 162-170, Vol. 275. | |
| SAFARIK, I. et al, "Magnetic Techniques for the Isolation and Purification of Proteins and Peptides," BioMagnetic Research and Technology, 2004, pp. 1-17, Vol. 2, No. 7. | |
| SHEVCHENKO, A. et al., "Deciphering Protein Complexes and Protein Interaction Networks by Tandem Affinity Purification and Mass Spectrometry," Molecular & Cellular Proteomics 1.3, 2002, pp. 204-212, Vol. 1. | |
| Complex and Mass Spectrometric Peptide Mapping," Proc. Natl. Acad. Sci. USA, December 1990, pp. 9848-9852, Vol. 87. | |
| Systems, "October 2004, pp. 779-790, Vol. 13, No. 5. | |
| VILLANEUVA, J. et al., "Serum Peptide Profiling by Magnetic Particle-Assisted, Automated Sample Processing and MALDI-TOF Mass Spectrometry," Analytical Chemistry, March 15, 2004, pp. 1560-1570, Vol. 76, No. 6. | |
| WANG, S. et al., "Proteomics Based on Selecting and Quantifying Cysteine Containing Peptides by Covalent Chromatography," Journal of Chromatography A., 2001, pp. 345-357, Vol. 924. | |
| WANG, S. et al., "Quantitative Proteomics Strategy Involving the Selection of Peptides Containing both Cysteine and Histidine from Tryptic Digests of Cell Lysates," Journal of Chromatography A, 2002, pp. 153-162, Vol. 949. | |
| | Detection," Analytical Chemistry, October 15, 1999, pp. 4727-4733, Vol. 71, No. 20. Jl. J. et al., "Strategy for Qualitative and Quantitative Analysis in Proteomics Based on Signature Peptides," Journal of Chromatography B, 2000, pp. 197-210, Vol. 745. KISELAR, J. G. et al., "Direct Identification of Protein Epitopes by Mass Spectrometry Without Immobilization of Antibody and Isolation of Antibody – Peptide Complexes," Analytical Chemistry, May 1, 1999, pp. 1792-1801, Vol. 71, No. 9. LACEY, J. M. et al., "Rapid Determination of Transferrin Isoforms by Immunoaffinity Liquid Chromatography and Electrospray Mass Spectrometry," Clinical Chemistry, 2001, pp. 513-518, Vol. 47, No. 3. LIPTON, M. S. et al., "Global Analysis of the Deinococcus radiodurans Proteome by Using Accurate Mass Tags," PNAS, August 20, 2002, pp. 11049-11054, Vol. 99, No. 17. MACCOSS, M. J. et al., "Shotgun Identification of Protein Modifications from Protein Complexes and Lens Tissue," PNAS, June 11, 2002, pp. 7900-7905, Vol. 99, No. 2. MUNCHBACH, M. et al., "Quantitation and Facilitated de Novo Sequencing of Proteins by Isotopic N-Terminal Labeling of Peptides with a Fragmentation-Directing Moiety," Analytical Chemistry, September 1, 2000, pp. 4047-4057, Vol. 72, No. 17. NEDELKOV, D. et al., "Design of Buffer Exchange Surfaces and Sensor Chips for Biosensor Chip Mass Spectrometry," Proteomics, 2002, pp. 4014-446, Vol. 2. NELISON, R. w. et al., "BlA/MS of Epitope-Tagged Peptides Directly from E. Coll Lysate: Multiplex Detection and Protein Identification at Low-Femtomole to Subferntomole Levels," Analytical Chemistry, 1999, pp. 2858-2865, Vol. 71. ODA, Y. et al., "Accurate Quantitation of Protein Expression and Site-Specific Phosphorylation," Proc. Natl. Acad. Sci. USA, June 1999, pp. 6591-6596, Vol. 96. ONG, S. E. et al., "Stable Isotope Labeling by Amino Acids in Cell Culture, SILAC, as a Simple and Accurate Approach to Expression Proteomics," Molecular & Cellular Proteomics II, 2002, pp. 496-4979, Vol. 74, No. 19. PETRICOIN, E. F. |

Approved for use through 07/31/2006. OMB 0651-0031

| Cb. | stitute for form 1449A/PTO | | Complete if Known |
|-------|-----------------------------------|------------------------|--------------------|
| Sub | stitute for form 1449A/F 10 | Application Number | 10/676,005 |
| IN | FORMATION DISCLOSURE | Filing Date | October 2, 2003 |
| | TATEMENT BY APPLICANT | First Named Inventor | Norman L. Anderson |
| 31 | STATEMENT BY ATTLICANT | Group Art Unit | 1645 |
| | (use as many sheets as necessary) | Examiner Name | Hines, Jana A. |
| Sheet | 4 of 4 | Attorney Docket Number | ANDE-001/04US |

| | 70. | WU, S-L. et al., "Targeted Proteomics of Low-Level Proteins in Human Plasma by LC/MS ⁿ : Using Human Growth Hormone as a Model System," Journal of Proteome Research, 2002, pp. 459-465, Vol. 1. | * |
|---|---|---|---|
| | 71. | YAO, X. et al., "Proteolytic ¹⁸ O Labeling for Comparative Proteomics: Model Studies with Two Serotypes of Adenovirus," Analytical Chemistry, July 1, 2001, pp. 2836-2842, Vol. 73, No. 13. | |
| 72. YU, L. et al., "Epitope Mapping of Complex Biological Systems," J. Ar | | YU, L. et al., "Epitope Mapping of Monoclonal Antibodies by Mass Spectrometry: Identification of Protein Antigens in Complex Biological Systems," J. Am. Soc. Mass. Spectrom., 1998, pp. 208-215, Vol. 9. | _ |
| | 73. ZHAO, Y. et al., "Mapping Protein-Protein Interactions by Affinity-Directed Mass Spectrometry," Proc. Natl. Acad. Sci. USA, April 1996, pp. 4020-4024, Vol. 93. | | |

| | Examiner | Date | |
|---|-----------|------------|--|
| 1 | Signature | Considered | |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

286305 v1/RE